REMARKS

Favorable reconsideration of this application is respectfully requested in view of the following remarks.

Appreciation is expressed to Examiner Bouchelle for returning signed and initialed copies of forms PTO-1449 submitted with the Information Disclosure Statements filed on March 26, 2004 and August 17, 2004. It is noted that the last document cited on form PTO-1449 submitted with the Second Information Disclosure Statement filed on August 17, 2004 was inadvertently not initialed. The Examiner is kindly asked to initial such document (European Application Publication No. 1 264 610) and return another copy of the initialed form PTO-1449 in the next official communication.

By way of this Amendment, Claim 16 has been canceled. Thus, the claims currently at issue in this application are Claims 1-15, with Claims 1, 13 and 15 being the only independent claims.

The subject matter of this application pertains to a catheter, a catheter system and a method for injecting a therapeutic composition. Claim 1 is directed to the catheter for percutaneous insertion and recites that the catheter comprises a sheath portion with a lumen extending therein, an insertion member disposed slidably in the lumen and provided with a distal end portion adapted to protrude from the distal end portion of the sheath portion, and an injection needle disposed in the distal end portion of the insertion member for injecting a therapeutic composition to a target tissue. In addition, the catheter comprises paired electrodes disposed in the distal end portion of the catheter for measuring impedance.

Claim 13 defines the catheter system in terms of a catheter for percutaneous insertion that comprises a sheath portion provided with a lumen, an insertion member slidably disposed in the lumen of the sheath portion and possessing a distal end portion adapted to protrude from the distal end portion of the sheath portion, and an injection needle disposed in the distal end portion of the insertion member for injecting a therapeutic composition. The catheter system further comprises paired electrodes disposed in a distal end portion of the catheter to measure impedance and a puncture detecting device to which conductors extending from the paired electrodes are adapted to be connected for detecting a puncture by the injection needle based on impedance values measured by the paired electrodes.

Finally, independent Claim 15 is directed to the method for injecting a therapeutic composition with a catheter that comprises the sheath portion, the insertion member, the injection needle and the paired electrodes. The claimed method involves inserting the catheter into a living body and advancing it to a neighborhood of the target tissue, puncturing the target tissue with the injection needle based on impedance values measured by the paired electrodes and injecting the therapeutic composition into the target issue.

The Official Action sets forth an anticipatory rejection of independent Claims 1 and 15 based on the disclosure in U.S. Application Publication No. 2002/0183738 to *Chee et al.* This document discloses a method and apparatus for treating tissue inside a patient's body. The disclosed apparatus includes a distal end probe 22, 130 provided with electrodes 48, 50, 136, 138, 140. As discussed in paragraph [0099] of *Chee et al.*, the electrodes operate to determine whether or not the probe is properly contacting the tissue surface. That is, the electrodes provide an indication of

whether or not the probe is contacting the tissue surface at an angle of 90°. *Chee et al.* describes that little or no contact between the probe and the tissue surface results in maximum current.

One significant difference between the subject matter of the present application and the disclosure in *Chee et al.* is that the paired electrodes are used to measure impedance to determine whether the injection needle has punctured tissue to thus reliably indicate that the injection needle is positioned in the tissue. To more clearly emphasize this aspect, all of the independent claims have been amended to recite that at least one of the paired electrodes is disposed at the distal end portion of the insertion member. The impedance value measured by the electrodes shows a relatively large identifiable difference between when the electrodes are present in the blood before the tissue is punctured with the injection needle and when at least one of the electrodes is positioned in the tissue after the injection needle has punctured the tissue.

In *Chee et al.*, the electrodes are disposed on the probe or sheath portion for purposes of determining the surface contact between the probe and the tissue surface. *Chee et al.* is not all concerned with providing one or more electrodes to determine whether a needle has punctured the tissue. There would thus be no reason to position the electrodes in the manner recited in the independent claims here. Further, considering the particular purpose for which the electrodes disclosed in *Chee et al.* are used (i.e., assessing whether or not the probe is contacting the tissue surface at an angle of 90°), there would have been no reason to move the electrodes to arrive at the arrangement recited in independent Claims 1 and 15 here. For at least that reason, it is respectfully submitted that independent Claim 1 and

dependent Claim 15 are patentably distinguishable over the disclosure contained in *Chee et al.*

Original dependent Claim 2 recites that the paired electrodes are disposed at the distal end portion of the insertion member. This claim was rejected based on the disclosure in *Chee et al.* in view of the disclosure in U.S. Patent No. 6,190,360 to *Iancea et al.* In light of the amendment to Claims 1 and 15 reciting the disposition of at least one of the electrodes at the distal end portion of the insertion member, this combination of references is addressed here in the context of Claims 1 and 15.

Iancea et al. describes in column 8 that a catheter 194 positioned within the distal portion 126 of a handle member 112 can be provided with a treatment element 196 in the form of an angioplasty balloon, a stent or other prosthesis, and/or an array of electrodes. Thus, the array of electrodes envisioned by *Iancea et al.* is a treatment element for treating a lesioned portion having disease.

The Official Action states that the disclosure in *Iancea et al.* of an array of electrodes provided on a catheter teaches that it would have been obvious to place the electrodes disclosed in *Chee et al.* on the insertion member. This position is respectfully traversed for several reasons. First, as discussed above, *Chee et al.* discloses the use of electrodes 136, 138, 140 for purposes of ascertaining whether or not the face or tissue-contacting portion 46 of the probe properly contacts the tissue surface at an angle of 90°. Considering this purpose, it would not have been obvious to one of ordinary skill in the art to place the electrodes on an insertion member within the probe because such a positioning of the electrodes is inconsistent with the purpose stated in *Chee et al.* for utilizing the disclosed electrodes 136, 138, 140. That is, it has not been established that positioning the electrodes 136, 138,

140 disclosed in *Chee et al.* on an insertion member within the probe would still allow the electrodes to serve their intended purpose of determining whether or not the tissue-contacting portion 46 of the probe properly contacts the tissue surface at an angle of 90°.

In addition, *Iancea et al.* discloses that the disclosed electrode array serves as a treatment unit for treating a lesioned portion having disease. This purpose for providing the array of electrodes is completely different from the stated purposes associated with the electrodes 136, 138, 140 disclosed in *Chee et al.* Thus, the disclosure in *Iancea et al.* would not have directed one of ordinary skill in the art to modify the positioning of the electrodes 136, 138, 140 disclosed in *Chee et al.* in the manner proposed in the Official Action.

Further, it is also significant to note that the electrode array disclosed in *Iancea et al.* serves a completely different purpose compared to the paired electrodes used in the present invention. As discussed above, the paired electrodes used here provide a mechanism for sensing that the injection needle has punctured the target tissue. *Iancea et al.* does not disclose using electrodes for this purpose.

For at least the reasons set forth above, it is respectfully submitted that a combination of the disclosures in *Chee et al.* and *Iancea et al.* would not have motivated one to provide a percutaneous insertion catheter and method as recited in independent Claims 1 and 15.

In addition, Claim 15 has been amended primarily to recite in a different manner that which was originally recited in Claim 15. That is, Claim 15 has been amended to recite that the method involves measuring impedance with the paired electrodes, moving the insertion member relative to the sheath member, protruding

the injecting needle from the distal end portion of the sheath portion to puncture the target tissue, and injecting the therapeutic composition through the needle into the target tissue after a change is detected in the impedance values as measured by the paired electrodes. A careful reading of the disclosure in *Chee et al.* reveals no disclosure of a method that involves measuring impedance with paired electrodes, moving an insertion member to protrude an injection needle from the distal end portion of the sheath, and injecting therapeutic composition through the needle and into the target tissue after a change is detected in the impedance value as measured by the paired electrodes. As pointed out above, *Chee et al.* is not at all concerned with utilizing a change in impedance value as measured by paired electrodes to determine that tissue has been punctured and thereby determine that it is appropriate to inject therapeutic composition through the needle into the target tissue. For this additional reason, it is respectfully submitted that independent Claim 15 is further distinguishable over the disclosure in *Chee et al.*

Addressing independent Claim 13, the Official Action cites *Chee et al.* together with U.S. Patent No. 6,165,164 to *Hill et al.* Here, the Official Action recognizes that *Chee et al.* lacks disclosure of a puncture sensing device and thus relies upon the disclosure in *Hill et al.*, stating that such document discloses a puncture sensing device. However, that is not an accurate assessment of the disclosure in *Hill et al.* The discussion at the bottom of column 2 of *Hill et al.* describes a drug injection catheter that includes a tip electrode mounted at the distal end of the tip section. The tip electrode is in the form of an electromagnetic mapping sensor 72 which allows a physician to map various aspects of the heart such as the contour or shape of the heart chamber, the electrical activity of the heart, etc. It is

significant to note that the mapping sensor described in *Hill et al.* is used *before* puncturing with the needle as discussed beginning near the bottom of column 7 and extending to the top half of column 8 of *Hill et al.* Thus, it cannot be said that the mapping sensor referenced in *Hill et al.* is a puncture detecting device as recited in Claim 13 since the mapping sensor has nothing to do with detecting puncture by a needle, let alone detecting puncture by a needle based on impedance values measured by the paired electrodes as recited in Claim 13.

Consequently, in addition to the reasons discussed above in connection with Claims 1 and 15 which are equally applicable to Claim 13, these additional arguments establish that a combination of the disclosures in *Hill et al.* and *Chee et al.* would not have led one to provide a catheter system as recited in independent Claim 13.

In the event the Examiner continues to believe that the disclosure in Hill et al. has some relevance to the claimed subject matter recited in Claim 13, the Examiner is kindly asked to explain such position in more detail so that the Examiner's position will be understood.

Addressing some of the additional dependent claims, the Official Action notes that *Chee et al.* does not disclose electrodes located not less than 1 mm from the leading edge of the insertion needle as recited in, for example, Claim 3. The Official Action thus relies upon the disclosure in U.S. Application Publication No. 2001/0031942 to *Tollner et al.* That rejection is respectfully traversed.

In the case of the invention at issue here in which at least one of the paired electrodes is separated by not less than 1 mm from the leading end of the bevel of the injection needle, it is possible to reliably detect sufficient puncture by the injection

needle because the leading end of the bevel of the injection needle has already been moved and placed in the tissue when the at least one of the paired electrodes moves into the tissue to produce a change in the impedance value. *Tollner et al.* does not disclose utilizing electrodes for the same purpose as that associated with the present invention.

Rather, what *Tollner et al.* describes is sensing electrodes 6, 7 embedded in the jacket 8 of an ablation electrode 3 for a completely different purpose. The Official Action has not established why one of ordinary skill in the art would have been motivated to utilize the disclosure in *Tollner et al.* in the device disclosed in *Chee et al.* As pointed out above, the electrodes described in *Chee et al.* serve the specific purpose of determining whether or not the probe is in proper contact with the tissue surface at an angle of 90°. *Tollner et al.* does not disclose that electrodes used for such a purpose should be positioned in the manner disclosed in *Tollner et al.* Rather, the electrodes disclosed in *Tollner et al.* serve a completely different purpose from that disclosed in *Chee et al.* Consequently, one of ordinary skill in the art would not have been motivated to modify the positioning of the electrodes disclosed in *Chee et al.* based on the disclosure in *Tollner et al.*

Addressing Claim 10, the Official Action cites U.S. Patent Application Publication No. 2003/0032936 to *Lederman* for its disclosure of a through hole communicating with a lumen. The Official Action takes the position that this disclosure in *Lederman* would have directed one to provide a similar hole in the sheath disclosed in *Chee et al.*

Lederman discloses a side port 16 that is specifically used to discharge therapeutic or diagnostic agents. However, the Official Action does not explain why

it would be necessary or desirable to provide a side hole in the sheath disclosed in *Chee et al.* for purposes of delivering therapeutic or diagnostic agents, particularly as *Chee et al.* already discloses delivering a tissue damaging agent by way of the needle.

It is also to be noted that the through-hole recited in independent Claim 10 serves to stabilize the impedance values by virtue of the electrodes on the insertion member inside the distal end portion of the sheath portion coming into contact with the blood more uniformly before the injection needle is protruded from the distal end portion of the sheath portion to puncture the tissue. This is of course quite different from the reason described in *Lederman* for providing a side hole.

For at least the reasons set forth above, it is respectfully submitted that all of the claims at issue here are patentably distinguishable over the various documents relied upon in the Official Action. Accordingly, withdrawal of the rejections of record and allowance of this application are earnestly solicited.

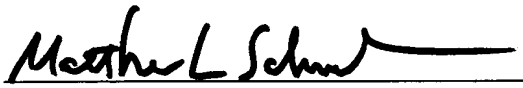
Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful

in resolving any remaining issues pertaining to this application the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

BUCHANAN INGERSOLL PC

Date: December 22, 2005

By: 
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